UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,154	09/25/2000	Kaare M. Gautvik	016777/0433	2686

7590 03/27/2002

FOLEY & LARDNER
3000 K Street NW
Suite 500
Washington, DC 20007

EXAMINER
HILL, MYRON G

ART UNIT	PAPER NUMBER
1648	5

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/668,154	GAUTVIK ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 25 September 2000 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is on claim 21 as added by preliminary amendment of the instant application. Claims 1- 20 were canceled by the same amendment.

Specification

The disclosure is objected to because of the following informalities: The specification contains numerous typographical errors, for example "market" on page 9 line 37. Appropriate corrections are required.

Drawings

The section "Brief Description of the Drawings" should refer to figures with multiple parts as such, for example Figure 9a and 9b. Also, see attached form PTO-948.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if applicant is claiming hPTH or an analog, such as $hPTH_{Q26}$.

The term "maximal response" in claim 21 is not clearly defined. There are many ways of measuring activity, and it not clear how "maximal response" is defined. Maximal

under what circumstances? It is not possible to look to the specification for an understanding of the intended meaning of "maximal response," since the phrase is not used in the specification.

Also, the phrase relating to responses "greater than which can be achieved by synthetic hPTH" is a relative term which renders the claim indefinite. It is not clear that there is one defined standard for synthetic hPTH.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "maximal response" constitutes new matter. Applicant is requested to point to support for "maximal response" in the specification as filed, as support for the claim limitation is not apparent to the Examiner.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention. The specification does not teach one that the claimed purified "hPTH" is better than synthetic hPTH. Figure 15, described on page 10, shows that the controls have AC activity as good as or better than the claimed purified product. The control/ standard, a synthetic hPTH from Sigma appears to have a higher peak activity and has a greater unit activity (AC activity per microgram of product assayed). Example 16, page 41, shows another comparison were a difference was shown. However, this is a comparison of a synthetic hPTH from Bachem and the $hPTH_{Q26}$ product which is an analog so the comparison is not between purity or quality of the same product. Also, it is not clear that biological activity in Example 16 at the four hour time point can be extrapolated to indicate the level at which calcium will be at after longer treatment and the if difference is maintained over the synthetic product, and it is not clear how relates to AC assay activity. It is also not clear that the two synthetic products chosen represent the full range of products on the market and therefore, show what the maximum limit of activity that can be achieved by the synthetic product. Also, it is not clear how to purify the product to achieve "maximal response" because no maximal response was shown with the claimed product in the AC activity shown in figure 15 and there is no demonstration that increased purity yields an increase in response from one level to a "maximal" level. Finally, the specification in Example 14, page 39 lines 18- 24, clearly states that the analog was compared to the synthetic and found to be equally as potent in stimulation in the AC assay.Thus, the specification has not shown a hPTH of the claims that has a maximal response over synthetic hPTH. Since the specification does not teach any purified product with the properties recited in the claim, it is concluded

that undue experimentation would be required to practice the purification method claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Olstad et al., Peptides 1994, 15 (7) 1261-1265. In making this rejection, applicant is denied the benefit of the filing dates of prior applications because the prior applications do not describe the process as now claimed.

Olstad compares activities of several parathyroid hormone (PTH) preparations. From the Results section, the following was disclosed in experimental comparisons of chemically synthesized and PTH(Q26):

Figure 1 shows that chemically synthesized and PTH(Q26) have similar binding affinities, Figure 2 shows that synthetic PTH does not stimulate as much intracellular cAMP production, Figure 3 shows that in an hypercalcemic assay the synthetic PTH was almost similar to the recombinant PTH(Q26),Figure 4 shows in the tubular reabsorbtion of phosphate assay that the potencies were similar, and Figure 5, the measurement of cAMP in urine, the chemically synthesized showed a smaller effect but it was concluded, there was no principal difference in the preparations in stimulation in this assay.

They conclude that their in vivo studies show that recombinant PTH is at least as potent as synthetic PTH (page 1264, last paragraph).

Olstad shows that under one condition (Figure 2) that PTH(Q26) has more activity but overall the effects were similar between chemically synthesized and PTH(Q26). Also, it is noted by the Examiner that some recombinant PTH without the Q26 mutation has better activity than the recombinant Q26 version, see Figures 4 and 5.

Olstad clearly anticipates that there is some difference between chemically synthesized and PTH(Q26) in certain assays.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
March 21, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600

1600